Grand Valley State University Human Research Review Committee	
Title: *Research non-compliance*	
Section: 1030.	This policy and procedure supersedes those previously drafted
Approved by HRRC: 02/14/2012 Revised by HRRPPC: 04/24/2018	Approved by RIO/HRPA: 02/16/2012 Revisions approved by AIO/RIO: 05/23/2018
Effective Date: 01/21/2019	
Related documents: *341: Unapproved research* *730: Collection, management and security of research information* *1010: Modifications to approved protocols* *1020: Unanticipated problems and adverse events* *1040: Research post-approval audits* *1050: Suspension or termination of research activities* *1060: Closures of approved research studies* *1070: Responding to concerns and complaints about human subjects research activities* *OP-3: GV policy on research integrity*	

Policy

All members of research teams involved in research on living human subjects must comply with applicable federal, state, and local laws, research ethics standards and the determinations, policies and directives of the HRRC, or other oversight authority such as study sponsors, or collaborating educational and private institutions as appropriate. The study Principal Investigator (PI), all members of research teams, and the protocol authorizing official are responsible for reporting known or suspected incidents of non-compliance to the GVSU Office of Research Compliance and Integrity (ORCI), HRRC, and/or Research Integrity Officer (RIO).

Research misconduct and research non-compliance are distinct and separable violations of required research protections. Research non-compliance may be minor or serious, isolated or continuing. Federal regulations require reporting to the ORCI findings of either serious or continuing noncompliance (45 CFR 46.108(a)(4)(i)). Allegations of research misconduct are handled under a separate university policy and procedure (42 CFR 93).

Definitions

1. *Research Misconduct*. In the GVSU policy and procedures on Research Integrity (revised, 2012), research misconduct (RM) is defined as the fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results, and/or engaging in ordering, advising or suggesting that subordinates engage in misconduct in research, scholarship or creative activities. RM does not include honest error or differences of opinion. The RM offenses are defined as:

    a. *Fabrication*: making up data or results and recording or reporting them.
    b. *Falsification*: manipulating research materials, equipment, or processes, or changing or omitting data or results such that research is not accurately represented in the research record.
    c. *Plagiarism*: the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

2. *Research Non-compliance*: Non-compliance is defined as failure by any member of the research team to comply with applicable federal, state, or local laws, research ethics standards or with the determinations, policies and directives of the HRRC, or other oversight authority such as study sponsors, collaborating educational or private institutions, etc. Non-compliance may be serious or non-serious, and isolated or continuing.

    a. *Serious Non-compliance*. Non-compliance is serious when the action or omission poses a greater than minimal risk to research participants.
    b. *Continuing Non-compliance*. Non-compliance is continuing if it is not an isolated event but consists of actions or omissions repeated over time affecting one or more research protocols.

Procedures

1. Reports of Non-Compliance

    Any person with direct knowledge or reasonable suspicion of research non-compliance must report that information directly to the ORCI, and/or HRRC Chairperson, and/or RIO. If willing, the person with direct knowledge of potential research non-compliance may also report that information to the PI. If reported to the PI, the PI shall take immediate corrective action to reduce or eliminate any imminent risk to participants that is posed by the potential reported non-compliance.

2. Non-Compliance Investigations and Determinations

    a. Assessment of Risk to Study Participants. The ORCI, the HRRC chairperson, and the RIO will conduct an initial assessment of the reported non-compliance and determine the immediate procedural steps required to reduce or eliminate any risk to currently enrolled or future research study participants. If the reported non-compliance affects an HRRC-approved study and the risk minimization procedures include suspension or termination of some or all research related procedures and interventions, the HRRC chair and RIO shall inform the PI. See: ***Policy 1050: Suspension or Termination of Research Activities.***

    b. The ORCI, HRRC Chairperson, and RIO will respond to the report of non-compliance per HRRC ***Policy 1070: Responding to concerns and complaints about human subject research activities.*** Reports of non-compliance related to research activities that lack HRRC approval will be forwarded as information to the university RIO. See: HRRC ***Policy 341: Unapproved Research.***

    c. If the reported non-compliance is determined by the ORCI, the HRRC Chairperson, and the RIO to have sufficient merit for an inquiry then a plan for an administrative inquiry will be developed. The RIO shall submit a written statement summarizing the initial assessment and the inquiry plan (if any) to the principal investigator, the PI's authorizing official, the Chairperson of the HRRC, and other individuals as deemed appropriate by the RIO.

d. Following the formal administrative inquiry, the RIO shall submit a written report summarizing the formal inquiry proceedings and findings to the PI, the PI's authorizing official, and other individuals as deemed appropriate by the RIO.

e. The PI will have ten business days to respond to the report in writing and submit the response to the RIO. Subsequent actions will be determined by the RIO in consultation with university counsel and other individuals as deemed appropriate by the RIO.

f. In addition, the written report shall be distributed to the following individuals or offices as appropriate:

    i. Study sponsors
    ii. Federal agencies such as the FDA or OHRP in compliance with reporting requirements
    iii. Other relevant internal and/or external entities as appropriate

g. All findings of non-compliance will be summarized and included in the annual report to the HRRC and will be documented in the protocol file along with any administrative response, as appropriate.